

Appln No.: 08/935,717

Amendment Dated: November 7, 2003

Reply to Office Action of January 2, 2003

REMARKS/ARGUMENTS

In lieu of an Appeal Brief, Applicants submit this amendment and an accompanying Request for Continuing Examination.

Applicants an extension of time sufficient to make this paper timely and enclose the appropriate fee. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 15-0610.

In an Advisory Action mailed August 28, 2003, that the amendment to claim 12 proposed therein would raise issues of new matter. Claim 12 as amended herein uses the language from the specification (Page 3, lines 29-35) which the Examiner quoted in the Advisory Action. Accordingly no issue of new matter should be raised by this amendment, and the amendment should overcome the prior rejection under 35 USC § 112, second paragraph.

Claim 31 has been added, dependent on claim 11, and containing the limitation of claim 17. Claims 32-36 are also added. These claims correspond to prior claims 13-17, except that claim 32, the first in the series, is dependent on claim 1, rather than claim 2.

The Examiner indicated that claims 17-18, 23-24 and 28-30 were allowable over the art.

Claims 11-16, 19-22 and 25-27 were rejected in the Office Action of January 2, 2003 as anticipated by US Patent No. WO95/13531. During a telephone conference, the Examiner indicated that greater significance may be being given to this reference because it had the same inventors and contained many of the same drawings and terminology than would have been given had the present application been by a third party. Applicants respectfully submit that the identity of the author of a prior art reference is of no relevance in establishing its significance.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants respectfully submit that the present invention is different from the test kit disclosed in WO95/13531 and that the reference therefore cannot be deemed to be anticipatory. In the present invention, as defined in claim 11, the following limitation is found:

a means for initiation of the reading device that engages the assay device in a lock and key relationship.

The Examiner states that this limitation is met by the cited reference at Page 5, lines 5-10. This paragraph, however, reads:

Preferably, said receiving means incorporates interlocking means engagable with

Appln No.: 08/935,717

Amendment Dated: November 7, 2003

Reply to Office Action of January 2, 2003

corresponding interlocking means on said device to ensure that upon receipt of said device by said reader said detection zone(s) is located and maintained in a predetermined spacial relationship relative to said reading means.

This paragraph teaches only that the lock and key arrangement ensures proper placement in the reading device. There is no teaching of a lock and key interaction being made with the initiation means. Furthermore, this paragraph cannot be read in isolation from the teaching of the reference as a whole.

The Catt reference, over which the present invention is an improvement, discloses a lock-and-key interaction between an assay device and a reading device. The reading device has an initiation switch, i.e., reference numeral 504. However, as previously noted, in Catt, the reading initiation switch does not participate in the formation of the lock-and-key interaction with the assay device. Note that in Figs. 5 and 6 of Catt, the actuating means is the depressable button 504 "which must be fully depressed to activate the reading mechanism." (Catt, Page 24, line 27-29). The button mechanism does not function, and is not said to function, as a part of the lock-and-key interaction system. In contrast, as reflected in the discussion of Fig. 9 on Pages 11, line 7 et seq., the reading device has protrusions 301, 302 which fit precisely within recesses 703, 704 on the assay device, i.e. in a lock-and-key interaction, "to provide a unique three-dimensional situation in which the switch actuator is actuated by the received assay device."

The Examiner also cites several portions of the disclosure as teaching that "the reading device is initiated when the assay device is positioned correctly within the reading device in the lock and key arrangement." As a first matter, the claims state that the reading device is initiated **only** when the lock and key arrangement is complete. The Examiner statement of the teaching of the reference is broader than the limitation in the claim. Furthermore, the statements cited by the Examiner fall far short of requiring a completed lock-and key engagement as a start of the reading cycle. For example, the passage at Page 26, lines 5-7 relates to structures on the facing surfaces of the reading device and the assay device which insure that the assay device is not inserted upside down. They do not ensure complete insertion in the correct position prior to initiation of the read cycle, because they do not teach a lock and key interaction between the **reading initiation means** and the assay device. The remaining citations all refer to a lock and key positioning of the assay device relative to the detection system, and thus also fail to teach the present invention. In particular, note that the button or projection 305 referred to at Page 18, lines 1-4 is not said to be a reading initiation means, and indeed is analogous to Fig. Numeral 506 in Fig. 6. Thus, Catt does not anticipate claim 11, nor any of the claims dependent thereon.

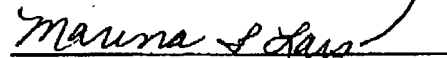
The Examiner states in the Advisory Action mailed June 18, 2003 that Catt discloses a combination "wherein said receiving means includes actualting means triggered by said receipt of said device, said actuating means causing said reading of said detection zone(s) to be initiated." She further asserts that "clearly this section defines the inter-relationship of the assay device, the detection zone, and initiation means." She continues, however, that "the initiation of reading ... results **only** upon receipt of the device in the correct lock and key relationship within the receiving means." Nothing in the reference actually supports this conclusion, since, as explained above, there is no connection in the reference between the lock and key relationship and the initiation of reading. Indeed, the portion of the disclosure relied upon by the Examiner is a

Appln No.: 08/935,717
Amendment Dated: November 7, 2003
Reply to Office Action of January 2, 2003

claim, which is necessity must be interpreted in light of the specification. Thus, the Examiner's assertion of anticipation is incorrect and the rejection should be withdrawn.

For these reasons, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully Submitted,


Marina T. Larson, Ph.D
Attorney/Agent for Applicant(s)
Reg. No. 32038

(970) 468 6600